Lori G. Cohen Tel 678.553.2385 Fax 678.553.2386 cohenl@qtlaw.com

July 27, 2021

VIA ECF

The Honorable Robert B. Kugler United States District Court Judge District of New Jersey Mitchell H. Cohen Building & U.S. Courthouse 4th & Cooper Streets Room 1050 Camden, NJ 08101

Special Master the Honorable Thomas Vanaskie Stevens & Lee 1500 Market Street, East Tower 18th Floor Philadelphia, PA 19103

> Re: <u>In re Valsartan, Losartan, and Irbesartan Products Liability Litigation</u> Case No. 1:19-md-02875-RBK-JS

Dear Judge Kugler and Special Master Vanaskie:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the Case Management Conference with the Court on July 28, 2021. The parties have conferred and do not expect the need to discuss any confidential materials as part of these agenda items. .

1. ZHP's Alleged Waiver of Certain Confidentiality Designations

On July 16, 2021, Plaintiffs filed their brief in support of their contentions that the ZHP Parties waived certain confidentiality designations. This was two days after the Court-ordered deadline for the submission of this brief. The ZHP Parties filed their brief in response on July 22, 2021. Consequently, from the ZHP Parties' perspective, this motion has been fully briefed and awaits the Court's decision on the papers or following oral argument. On July 23, 2021, Plaintiffs filed a letter seeking leave to file a reply brief to respond to the ZHP Parties' contention that

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Plaintiffs' opening brief was untimely. *See* letter from Adam Slater dated July 23, 2021 (ECF No. 1406). For the reasons set forth in the ZHP Parties' letter in response to Mr. Slater's letter of July 23, dated July 26, 2021 (ECF No. 1407), the Court should deny Plaintiffs' request to file a reply brief. Alternatively, should the Court permit the submission of plaintiffs' reply brief, the ZHP Parties respectfully request that any such reply brief be limited solely to the issue of the timeliness of Plaintiffs' initial brief. (*See* ECF No. 1406.)

2. Hetero Privileged Documents Dispute

Defendants Hetero Drugs Ltd. and Hetero Labs Ltd. (collectively, "HLL") have been engaged in ongoing discussions with Plaintiffs regarding its privilege log and have thus far made four document productions to de-designate documents previously deemed privileged. Currently, there is a narrow, discreet set of documents for which HLL will continue to assert its privilege or partial privilege designations.

On July 9, 2021, Plaintiffs raised specific objections with respect to documents deemed privileged, or partially privileged with redactions, in HLL's privilege log. In response, on July 26, 2021, HLL made a document production de-designating 4 documents that were previously deemed privileged. Presently at issue are 26 documents and emails contained in HLL's privilege log for which HLL asserts a privilege, or a partial privilege with redactions. These documents include attorney communications setting forth strategy, attorney work product and drafts, as well as attorney mental impressions. HLL will continue to assert its privilege designations with respect to these 26 documents, which Plaintiffs have failed to set forth a basis to require de-designation.



3. Retail Pharmacy Defendant Draft Deposition Notice

The Retail Pharmacy Defendants have conferred with Plaintiffs on several occasions regarding Plaintiffs' draft 30(b)(6) notice, and believe they are close to agreement with Plaintiffs regarding the draft topics. If the parties cannot agree to the notices by July 30, the parties intend to ask Your Honor for an off-cycle telephonic conference the week of August 2nd to address any lingering issues so the notices can be finalized and entered by the Court.

4. Wholesaler Defendant Draft Deposition Notice

Plaintiffs and Wholesaler Defendants continue to meet and confer concerning Plaintiffs' proposed Rule 30(b)(6) Notice of Deposition to Wholesaler Defendants ("the Notice"). Wholesaler Defendants anticipate that the parties are closing in on an agreement to a set of topics for the Notice. If the parties are unable to finalize an agreement on a set of topics for the Notice by July 30th, the parties intend to ask Your Honor for an off-cycle telephonic conference during the week of August 2nd to address any issues that remain in dispute.

5. Experts Kumar and Bird disclosed by Individual Plaintiff Counsel Parafinczuk

Separate from the five general causation expert reports submitted by the Plaintiffs' Executive Committee, the Parafinczuk Wolf law firm submitted the expert reports of Nagi Kumar, Ph.D., R.D., FADA, and Steven Bird, M.D. on behalf of a small subset of Plaintiffs represented exclusively by that firm. In disclosing Drs. Kumar and Bird, the Parafinczuk Wolf law firm specifically stated that "Plaintiffs represented by undersigned counsel . . . hereby file their Notice of Serving Expert Report Addressing General Causation and Availability for Deposition." (ECF No. 1364) (emphasis added); (ECF No. 1365) (emphasis added). Additionally, when Plaintiffs' Executive Committee provided a report to this Court summarizing their expert disclosures, they GREENBERG TRAURIG, LLP ■ ATTORNEYS AT LAW ■ WWW.GTLAW.COM



listed the five PEC disclosed experts but did not reference Drs. Kumar or Bird to the Court (or Dr. Brautbar, for that matter).

When the issues related to the general causation expert reports were previously heard by the Court, Plaintiffs did not raise the possibility that individual plaintiffs or their counsel would be submitting their own reports on general causation. See generally, 11-24-20 Hrg. Tr. As expressly stated in the Order creating this MDL, "centralization will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation[]," and, importantly, "[c]entralization will eliminate duplicative discovery; prevent inconsistent pretrial rulings, including with respect to class certification and *Daubert* motions; and conserve the resources of the parties, their counsel, and the judiciary." (ECF No. 1.) The Manual on Complex Litigation further emphasizes with respect to discovery that "[p]resumptive limits should be set early in the litigation[,]" and "[i]n determining appropriate limits, the court will need to balance efficiency and economy against the parties' need to develop an adequate record for summary judgment or trial." Manual Complex Litigation (4th Ed.) 53. available on at at https://www.uscourts.gov/sites/default/files/mcl4.pdf.

Defendants attempted to meet and confer over these reports with both the Plaintiffs' Executive Committee and the Parafinczuk Wolf law firm, to no avail. As Defendants expressed, in addition to being inconsistent with this Court's prior instruction, the expert reports are in part duplicative of those that the Plaintiffs' Executive Committee submitted, and Plaintiffs' counsel have made no attempt to coordinate, compare or reconcile the reports. Plaintiffs' Lead Executive Counsel readily admitted during the meet and confer that he had not even read the Kumar and Bird reports submitted by the Parafinczuk Wolf law firm. In an effort to avoid a dispute concerning GREENBERG TRAURIG, LLP ■ ATTORNEYS AT LAW ■ WWW.GTLAW.COM



these reports, Defendants proposed a compromise wherein Defendants would include these reports in the current phase of expert discovery and respond now if the parties could agree on a modest adjustment to the expert deadline and work together to schedule the depositions of Drs. Kumar and Bird. Unfortunately, Defendants' proposal was rejected and Defendants must now seek the Court's guidance as to how to proceed given the schedule did not contemplate the service of expert reports by individual plaintiffs or their counsel.

6. Expert Brautbar disclosed by Individual Plaintiff Counsel Bonanno in the Colon Case

On July 6, 2020, counsel for Plaintiff Danny Colon served the expert report of Nachman Brautbar, M.D., who presented his opinion that exposure to NDMA increases an individual's risk of developing amyotrophic lateral sclerosis ("ALS"). To Defendants' and Counsel Bonanno's knowledge, this is the *only* case in the entire MDL alleging ALS. Defendants have communicated to Plaintiff Colon's counsel and to the Plaintiffs' Executive Committee that Defendants are not required to respond to Dr. Brautbar's report at this time, as the Court's scheduling order related to general causation did not contemplate service of expert reports related to diseases other than cancer. At the November 24, 2020 hearing setting the schedule for general causation expert reports and the related *Daubert* briefing, there was no discussion or argument related to general causation of diseases other than cancer. *See generally*, 11-24-20 Hrg. Tr. Indeed, one of the primary issues resolved by the Court at that hearing related to whether Plaintiffs were required to go a step further and disclose the specific types of cancer that would be the subject of the expert reports prior to the service thereof:

I do agree the plaintiffs need to start delineating very soon the cancers which they believe were caused by . . . these substances. We need an identification of where the plaintiffs think this is going to go.



11-24-20 Hrg. Tr. at 13:15-21. Thereafter, Plaintiffs were ordered to disclose the types of cancer on which they would offer expert opinions, and did so on December 31, 2021. (*See* ECF No. 706.)

Not only does the report of Dr. Brautbar fall outside of the scope of the Court's order on general causation, it raises the question as to whether Plaintiff Colon's claims are properly before this Court given the JPML's order that centralized personal injury claims be related to cancer:

Although all pending actions on the motion before us are putative consumer class actions seeking economic damages, we received extensive briefing and oral argument on whether the MDL should include personal injury actions. Based on this record, we believe that the centralized proceedings should include the related personal injury actions *alleging that plaintiffs developed cancer* as a result of using valsartan containing NDMA or NDEA impurities.

(ECF No. 1 at 3 (emphasis added)). Because ALS is an individualized and specific injury to a single Plaintiff, Defendants submit that Dr. Brautbar's report, deposition and any response or rebuttal thereto is more appropriately dealt with at the specific causation phase of the case. Accordingly, Defendants respectfully request that the Court clarify that Dr. Brautbar's report does not fall within the general causation scheduling order and that any deadline to respond to Dr. Brautbar's report be held in abeyance.

7. Page Limits on Defendants' Surreplies to Plaintiff's Motion to Amend

On May 4, the Court granted Defendants' request for leave to file surreply briefs to Plaintiffs' Motion for Leave to Amend the Master Complaints. (ECF No. 1217). That order did not specify the number of pages of surreply briefing allowed for each defense group. Defendants therefore considered the 15-page limit afforded for reply briefs under the Court's local rules to govern page limits for the forthcoming surreplies.



Given the upcoming August 2 deadline to file surreplies, on July 26, Defendants reached out to Plaintiffs regarding this issue, and to see if Plaintiffs would consent to the Manufacturer Defendants, Wholesaler Defendants and Pharmacy Defendants each being afforded up to 18 pages for their respective surreplies. This request reflected Defendants' determination, after having considered the issues raised by Plaintiffs' motion and spent considerable time preparing initial drafts of their own briefs, of the number of pages each defense tier might reasonably require to address Plaintiffs' reply briefs. Plaintiffs responded that they do not consent, and believe that the 15-page limit for reply briefs under the local rules should govern.

Defendants respectfully request that the Court grant each defense group permission to file surreplies up to 18 pages in length (i.e. an additional 3 pages of briefing for each brief). Defendants submit that this request is very reasonable, given the significance of this briefing to the litigation as a whole, and given the number of issues raised by the parties' briefing to date.

8. Plaintiff Fact Sheet Show Cause Submissions

Cases Addressed at the June 25, 2021 Case Management Conference:

The Court issued two show cause orders returnable at the July 28, 2021 Case Management Conference:

- Stone, Alan v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al. 20-cv-15654
- Stewart, Pamela v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al. 20-cv-03788

Defendants reached out to individual counsel for both of these cases and have been available for further meet and confers as needed. Pursuant to those communications, the issues in the *Stone* matter are resolved and that show cause order may be withdrawn. The *Stewart* matter is not resolved, and Defendants request the show cause hearing proceed in this matter.



<u>Second Listing Cases – Order to Show Cause Requested:</u>

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these three cases were previously listed on the agenda for a prior CMC. In lieu of a global meet and confer, Defendants reached out to individual counsel for each case and have been available for further meet and confers as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why the case should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the July 28, 2021 Case Management Conference:

P	Plaintiff Civil Action No.	Law Firm	Deficiencies	Deficiency Notice Sent
Cas Aı	Henton, sandra v. urobindo ma, Ltd., et al.		I.C.10 – Failed to provide any response to the request to identify the repackager for the sixth identified product (with usage dates of 12/2014-01/2016). I.C.12 – Failed to provide the end date for the third identified Valsartan product (with an identified start date of 08/2016) or for the fourth identified Valsartan product (with an identified start date of 07/2016). III.C.5.a-III.C.5.b – Plaintiff's response of "N/A" in the Amended PFS is an insufficient answer to state whether Plaintiff was undergoing treatment that lasted for a minimum of 6 months for any	5/11/2021

				other conditions at the time	
				Plaintiff was diagnosed with	
				injury(ies) she attributes to	
				Valsartan use.	
				III.G.c – Failed to state the	
				monetary amount of each of the	
				identified claimed medical	
				expenses.	
				XI.A.1 – Plaintiff produced one	
				health care authorization for an	
				unspecified health care	
				provider. Please produce	
				properly executed and undated	
				health care authorizations for	
				each identified health care	
				provider, treatment facility, and	
				pharmacy.	
				XI.A.3 – Plaintiff asserted a	
				wage loss claim in the PFS,	
				however no employment record	
				authorizations were produced.	
				Please produce properly	
				executed and undated	
				employment record	
				authorizations.	
				XI.A.6 – Failed to produce any	
				insurance records	
				authorizations. Please produce	
				properly executed and undated	
				insurance records for each	
				identified insurance carrier.	
				XI.B.4 – Failed to respond. XI.B.17 – Plaintiff asserted a	
				wage loss claim, however no	
				corresponding W-2's or tax	
				returns were produced.	
				XI.B.18 – No corresponding	
				billing records were produced	
				for Plaintiff's claimed medical	
				expenses.	
2.	Righteous,	20-cv-	PWB Law Group, LLC	Incomplete PFS, no	4/23/21
	Worikeena v.	414		authorizations or records	
	Mylan et al.				



The following Plaintiff Fact Sheets contains core deficiencies which remain unresolved. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Russell, Sandra v. Camber Pharmaceuticals, et al.	21-cv- 10021	Curtis Law Group	I.C.8 – Camber is still identified as an API Manufacturer in the Second Amended PFS. However, Camber is not a manufacturer. This is inconsistent with the SFC. Please clarify. I.D.2 – No medical records were produced for Plaintiff's treatment with the identified physicians who prescribed Valsartan to Plaintiff, specifically: Balogh Atila and J. Race. Please produce complete medical records for Plaintiff's treatment in relation to the alleged injury(ies). II.F.1.d – Please clarify whether the identified workers' compensation claim was also submitted to a government agency or not. III.C.2.a-III.C.2.e – Plaintiff identified a herniated disk/slip and fall injury in response to the requests to identify each noncancer physical injury claimed in this lawsuit, including: the non-cancer physical injury, illness or disability; when this/these injury(ies) or illness	6/15/2021

	first occurred; the approximate	
	date(s) of the hospital	
	admission; the approximate	
	date(s) of discharge from the	
	hospital; and the hospital	
	name(s) and addresses, however	
	this identified injury of a	
	herniated disk in 1994-1995 is	
	approximately 22 years before	
	Plaintiff's first identified	
	Valsartan usage date in 2016.	
	Please clarify.	
	III.G.a-III.G.c – Plaintiff failed	
	to respond to the requests to	
	identify her claimed medical	
	expenses in the Second	
	Amended PFS. Please clarify	
	whether Plaintiff is asserting	
	any claimed medical expenses	
	or not.	
	XI.A.1 – One health care	
	authorization for an unspecified	
	health care provider was	
	produced with the Second	
	Amended PFS. Please produce	
	properly executed and undated	
	health care authorizations for all	
	identified health care providers,	
	treatment facilities, and	
	pharmacies.	
	XI.A.4 – Plaintiff produced one	
	workers' compensation	
	authorization for an unspecified	
	entity with the Second	
	Amended PFS. Please a	
	properly executed workers'	
	compensation authorization for	
	each respective entity. Also, it	
	is unclear whether Plaintiff	
	submitted the identified	
	workplace injury claim to a	
	government agency or not. If	
	Plaintiff did file a workers'	
	compensation claim with a	
	government agency, please	
	produce properly executed	
	workers' compensation	
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2. Pina, Flora, Individually and Surving Spouse	21-cv- 08045	Fears Nachawati	authorizations for the respective government agency(ies). XI.A.6 – One insurance records authorization for an unspecified entity was produced with the Second Amended PFS. Please produce properly executed and undated insurance records authorizations for each identified insurance carrier. XI.B.18 – Failed to provide billing records. I.C.1 – The produced pharmacy records do not contain any NDC codes. Please produce complete	6/21/2021
Surving Spouse and next of kin of Enrique Pina, Deceased v. Hetero Drugs, Ltd., etal.			codes. Please produce complete pharmacy records that contain NDC codes. II.D.4.d – Plaintiff's answers to the requests to provide the date of exposures in Plaintiff's diet including red and/or processed meats and including smoked foods, salted meat and fish, and/or pickled vegetables in the Second Amended PFS is incomplete and is cut off on the form. Please provide the complete responses and include a supplemental page, if necessary. III.G.a-III.G.c – Failed to provide any substantive responses to the requests to identify Plaintiff's claimed medical expense; and the monetary amount of each claimed medical expense.	
			IV.B.1-IV.B.4 – Plaintiff's answer "N/A" is an insufficient response to the requests to identify the facilities where Plaintiff has received treatment, as Plaintiff identified receiving treatment at MD Anderson Cancer Center elsewhere in the Second Amended PFS.	

3.	Chambers, Emily v. Aurobindo Pharma, Ltd., et al.	21-cv- 08458	Watts Guerra, LLP	XI.A.1 – No health care authorizations were produced for the following: Wal-Mart (at both identified locations); Nadya Martinez; Elizabeth M. Sanders, MD; and Dr. Gumaro Garza. Please produce properly executed and undated health care authorizations for each of the foregoing health care providers, treatment facilities, and pharmacies. XI.B.2 – The produced pharmacy records do not contain NDC codes. Please produce complete pharmacy records that contain NDC codes. XI.B.18 – Please produce complete billing records in relation to Plaintiff's claimed medical expenses. I.C.8 – Plaintiff's response "Not applicable" is an insufficient answer to the request to describe Plaintiff's reasonable good faith efforts to identify the manufacturer of the Valsartan products used in her treatment, as Plaintiff stated "unknown" as the API Manufacturer for the fourth identified Valsartan product (with usage dates of 1/2/2015-7/31/2015). III.B.3.a – Plaintiff did not state whether the referenced packaging inserts and/or written instructions are in her possession. If so, please produce a copy of said packaging inserts and/or written instructions.	7/2/2021
				packaging inserts and/or written	

	IV.A.3 – Plaintiff did not	
	provide the approximate start	
	date for her treatment with Dr.	
	Dierdre Young-Cadore. Also,	
	Plaintiff did not provide the	
	approximate end date for her	
	treatment with Dr. Nortin	
	Hadler.	
	IV.B.3 – Plaintiff did not	
	provide the approximate start	
	date for her treatment with The	
	Sandhills Medical Group.	
	IV.D.3 – Plaintiff did not	
	provide the approximate start	
	date for her coverage wit First	
	Medicare Direct.	
	XI.A.1 – One health care	
	authorization was produced for	
	an unspecified health care	
	provider. Please produce	
	properly executed an undated	
	health care authorizations for	
	each identified health care	
	provider, treatment facility, and	
	pharmacy.	
	XI.A.5 – Plaintiff produced one	
	disability records authorization	
	for records from "Emily	
	Chambers." Please produce	
	properly executed and undated	
	disability records authorizations	
	for each respective entity.	
	XI.A.6 – Plaintiff produce one	
	insurance records authorization	
	for records from "Emily	
	Chambers." Please produce	
	properly executed and undated	
	insurance records authorizations	
	for each identified insurance	
	carrier.	
	XI.B.18 – No corresponding	
	billing records produced for the	
	identified claimed medical	
	expenses from First Medicare	
	Direct.	
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5.	Orr, Helen v. Aurobindo Pharma, Ltd., et al. Thomas Lloyd v. Zhejiang Huahai	21-cv- 05481 21-cv- 12010	Williams Hart Boundas Easterby, LLP Rheingold Giuffra Ruffo Plotkin LLP	III.G.c – Plaintiff did not identify the monetary amount of the identified claimed medical expenses. XI.B.18 – Plaintiff did not produce any correspondence billing records in relation to the identified claimed medical expenses. FAILED TO RESPOND TO DEFICIENCY NOTICE	6/4/2021 7/1/2021
6.	Pharmaceutical Co., Ltd., et al. Lucinda Laughlin v. Zhejiang Huahai Pharmaceutical	21-cv- 08068	Williams Hart Boundas Easterby, LLP	III.G.c - Failed to state medical expenses for facilities listed.	6/23/2021
7.	Co., Ltd., et al. Billy Hupp v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al	21-cv- 04900	Levin Papantonio	III.G.c - Failed to state medical expenses.	6/23/2021
8.	Hector Rivera v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	21-cv- 10037	Morgan & Morgan	III.B.6.a - Failed to respond. Identify the advertisement or commercial, state the nature and content of each advertisement or commercial, and approximately when you saw the advertisement III.D.1 - Failed to respond. Current symptoms XI.A.1, 6 - Failed to provide properly signed, undated, and completed authorization.	7/1/2021
9.	Burlia Abdullahi v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	21-cv- 02885	Morgan & Morgan	XI.A.1, 4-6 - Failed to provide properly signed, undated, and completed authorization.	7/1/2021
10.	Estate of McClaskey v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al.	21-cv- 10037	Watts Guerra	III.G.c - Failed to state medical expenses.	7/2/2021

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11.	Marcia Ridley v.	21-cv-	Watts Guerra	III.G.c - Failed to state medical	7/2/2021
	Zhejiang Huahai	10045		expenses.	
	Pharmaceutical				
	Co., Ltd., et al.				
12.	Velma Hurst v.	21-cv-	Levin Papantonio	III.G.c - Failed to state medical	7/7/2021
	Zhejiang Huahai	04901		expenses.	
	Pharmaceutical				
	Co., Ltd., et al.				
13.	Debra Wright v.	21-cv-	Levin Papantonio	III.G.c - Failed to state medical	7/14/2021
	Zhejiang Huahai	01675		expenses.	
	Pharmaceutical				
	Co., Ltd., et al.				

<u>First Listing Cases – Failure to File Plaintiff Fact Sheet:</u>

The following Plaintiffs have failed to file a timely Plaintiff Fact Sheet. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

	Plaintiff	Civil Action No.	Law Firm	Deficiencies	PFS Due Date
1.	Shylaine Louissant	21-cv- 07797	Nagel Rice	No PFS Filed	06/12/2021
2.	Abraham Agustin	21-cv- 04480	Levin Papantonio	No PFS Filed	05/07/2021
3.	Robert Smith	21-cv- 09163	Levin Papantonio	No PFS Filed	06/12/2021
4.	Benita Smiley	20-cv- 20604	Serious Injury Law Group, Gerald Brooks, Esq.	No SFC or PFS filed	02/13/2021

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5.	Jimmie Thorn	20-cv- 20603	Serious Injury Law Group, Gerald Brooks, Esq.	No SFC or PFS filed	02/13/2021
6.	Daniel Craigie	20-cv- 12396	Bruce M. Danner, LLC	No SFC or PFS filed	11/01/2020
7.	Padrta, Lynda, Individually and as Anticipated Representative of E.O. Alan Martin, Deceased v. Hetero Drugs, Ltd., et al.	21-cv- 10480	Morgan & Morgan	No PFS Filed.	6/29/2021

Respectfully submitted,

<u>/s/ Lori G. Cohen</u>

Lori G. Cohen

cc: Adam Slater, Esq. (via email, for distribution to Plaintiffs' Counsel)
Jessica Priselac, Esq. (via email, for distribution to Defendants' Counsel)
Seth A. Goldberg, Esq. (via email)
Clem C. Trischler, Esq. (via email)
Sarah Johnston, Esq. (via email)
Jeffrey Geoppinger, Esq. (via email)